

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference BIOZI P29773PC	FOR FURTHER ACTION		See item 4 below
International application No. PCT/GB2004/001054	International filing date (<i>day/month/year</i>) 12 March 2004 (12.03.2004)	Priority date (<i>day/month/year</i>) 14 March 2003 (14.03.2003)	
International Patent Classification (IPC) or national classification and IPC 7 C07D 401/12, 405/14, 401/14, 409/14, 409/12, 413/12, 231/14, A61K 31/4155, A61P 29/00			
Applicant BIOLIPOX AB			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | |
|--|---|
| <input checked="" type="checkbox"/> Box No. I | Basis of the report |
| <input checked="" type="checkbox"/> Box No. II | Priority |
| <input type="checkbox"/> Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> Box No. VI | Certain documents cited |
| <input type="checkbox"/> Box No. VII | Certain defects in the international application |
| <input checked="" type="checkbox"/> Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

Date of issuance of this report
16 September 2005 (16.09.2005)

Authorized officer

Nora Lindner

Telephone No. +41 22 338 89 65

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. +41 22 740 14 35

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

REC'D 11 JUN 2004

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To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/GB2004/001054

International filing date (day/month/year)
12.03.2004

Priority date (day/month/year)
14.03.2003

International Patent Classification (IPC) or both national classification and IPC
C07D401/12, C07D405/14, C07D401/14, C07D409/14, C07D409/12, C07D413/12, C07D231/14, A61K31/4155,

Applicant
BIOLIPOX AB

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized Officer

Lauro, P

Telephone No. 449 89 2399-8288



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2004/001054

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material:
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing:
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2004/001054

Box No. II Priority

1. ☒ The following document has not been furnished:

- ☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).
☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-53
	No: Claims	
Inventive step (IS)	Yes: Claims	1-53
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-53
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V

1. Reference is made to the following documents:

D1: WO 99/25695 A (NODA YUKA ; OGINO TAKASHI (JP); MANABE TAKASHI (JP); FUJISAWA PHARMACE) 27 May 1999 (1999-05-27)

D2: TIHANYI E ET AL: "PYRAZOLECARBOXYLIC ACID HYDRAZIDES AS ANTIINFLAMMATORY AGENTS. NEW SELECTIVE LIPOXYGENASE INHIBITORS" EUROPEAN JOURNAL OF MEDICINAL CHEMISTRY, EDITIONS SCIENTIFIQUE ELSEVIER, PARIS, FR, vol. 19, no. 5, 1984, pages 433-439, XP000942814 ISSN: 0223-5234

2. **Novelty**

The compounds which would fall within the general formula (I) and which have all been disclaimed from claim 1 have been indexed in the CHEMCATS database and have not been cited in the Search Report. Since no activity is attributed to the compounds in CHEMCATS, the dependent claims which refer to the pharmaceutical use of the compounds of formula (I), including all the disclaimed compounds, are considered to be novel.

The compounds of the present application differ from the compounds disclosed in D1 and D2 in the nature of the substituents on the pyrazole ring.

3. **Inventive step**

The problem underlying the present application appears to reside in the provision of compounds useful in the treatment of inflammation in view of their inhibitory activity on the 5-lipoxygenase.

Pyrazole compounds at the 1- and 3-positions with groups as specified in claim 1 cannot be seen as obviously derivable from the antiinflammatory pyrazole derivatives disclosed in D1 or D2. Inventive step is acknowledged.

Re Item VIII

4. Claim 1 contains a series of disclaimers which render completely obscure the subject-matter which the claim intends to cover. Claim 1 lacks clarity.
5. Claim 49 refers to a method of treatment of the human body.